41. (added) The method as in claim 39 wherein the real-time ECG waveform is an ongoing display where absence of data is readily ascertainable and not crucial to implantable medical device operation.

REMARKS

Claims 1-35 have been cancelled, and claims 36-41 have been added. Claims 36-41 remain pending in the application. The applicant hereby requests further examination and reconsideration of the application in view of the foregoing amendments and following response. Attached to this reply is a marked-up version of the changes made to the specification labeled "Amended Specification Version With Markings To Show Changes Made" and a marked-up version of the changes made to the claims labeled "Amended Claims Version With Markings To Show Changes Made."

Claim/Specification Objections

Claim 1 stands objected to under 37 C.F.R. 1.75(a)-(d) because of the following informality: the use of the following acronym "SPC" and "PC" is noted in the instant application's claim. Claim 1 has been cancelled, so it is believed that the objection is no longer relevant. Also, the newly added claims do not contain these acronyms.

The specification stands objected to because of the multiple use of acronyms that are not spelled-out at their initial recitation in the disclosure. It is respectfully submitted that "QRS" is not an acronym but arbitrary letter that designate points on a waveform that represent ventricular depolarization. It is believed that the parenthetical (ventricular depolarization) added to page 16, para 3 (once amended) clarifies these letters. It is also respectfully submitted that "TAG" on page 21, para 1 is not an acronym but a term that

means an identifying label. It is believed that the amendment to this paragraph "Tag" clarifies that the term is not an acronym. It is submitted that the amendments to the specification overcome this objection by clarifying these acronyms and other terms.

Claim Rejections -- 35 U.S.C. § 103(a)

Claims 1-3 and 7-10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy U.S. Patent No. 6,312,387. Claims 1-3 and 7-10 have been cancelled. It is submitted that added claims 36-41 overcome this rejection. Claim 36 (added) includes the limitation of "transmitting and receiving a first data stream between the server and a client computer over a network wherein the client computer sends a receipt upon receiving the first data stream from the server and the server sends the receipt upon receiving the first data stream from the client computer; and, transmitting a second data stream between the server and the client computer over a network wherein the server sends the second data stream to the client computer and the client computer sends the second data stream to the server and transmitting the second data stream occurs free from sending receipts." It is submitted that Brady col 5/lines 60-66 does not teach or allude to the claimed first data stream and second data stream. Rather, it is submitted that Bardy describes well-know communications connectivity means. It is submitted that, although features (i-iv) described on pages 3-4 of the Office action are individually inherent in to the TCP/IP suite protocol, these general features are not being claimed. It is submitted that the claimed combination of a first data stream and second data stream are novel and nonobvious over the prior art.

In view of the above, it is submitted that all claims pending in the application are in condition for allowance. Accordingly, allowance of claims 36-41 is respectfully requested.

Respectfully submitted,

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Attachments:

- Amended specification paragraphs with markings;
- Amended claims with markings; and,
- Associate power of attorney

Amended Specification Version With Markings To Show Changes Made

Page 3, para 2 (once amended). A system permitting the remote communication with a medical device. The system particularly may permit the remote communication such that one or more device experts such as physicians and more experienced ~~-~~device users may be aware of the communication and provide guidance for the subsequent interpretation and programming of the device. The system may include a medical device adapted to be implanted into a patient; a ~~s~~Server Personal Computer (SPC) communicating with the medical device, the SPC having means for transmitting data across a dispersed data communication pathway (Internet); and a client Personal Computer (PC) having means for receiving data transmitted across a dispersed communication pathway from the SPC. In certain configurations the ~~the~~ server PC may have means for transmitting data across a dispersed data communication pathway (Internet) along a first channel and a second channel; and the client PC may have means for receiving data transmitted across a dispersed communication pathway from the SPC along a first channel and a second channel. Personal Computer (PC) is a registered trademark of International Business Machines Corporation.

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Page 8, para 3 (once amended). As seen, the system has essentially five primary components. Medical device 1 may be of any type which provides therapy to a patient or information collection so long as the device has the ability for communication (uaplink and downlink) to an external device, seen here as programmer 2. Medical device may, for example only and without limitation, comprise a Medtronic Kappa

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400 DDDR (Dual paced Dual sensed Dual response to sensing Rate modulation) pacemaker. Programmer 2 may, again, be of any acceptable design which permits linkage to a medical device including the Medtronic 9790 programmer.

Page 10, para 2 (once amended). In the present invention, the second data stream is used for transmission the ECG (Electro Cardio Graph), hence, the UDP data consists of only two bytes per message – one data point of the ECG waveform and its ordinal number. Apart from the ECG waveform, the cardiac therapy device could also send the IEGM, some hemodynamic parameter waveform such as blood pressure, blood flow, or even the ultrasound measurement waveform. UDP can be also used for transmission of the marker channels as well as of the various biochemical sensors signals. For example, within the context where the medical device is a nerve stimulator (similar to the Medtronic Itrel series) the device could transmit a EEG -or EGG waveform. In fact, a nerve stimulator having the capability to measure the tremor intensity would transmit the signal representing the tremor intensity thus enabling the DBS (Deep Brain Stimulation) output programming according to the tremor intensity. Since digitized waveforms have an inherent redundancy, in that the general waves are known as well as the possible values of the different parameters, missing data packets or missing data may be quickly identified as being actually missing, as opposed to indicating very low sensed and reported signal strength, or the data having peculiar values. UDP packets are satisfactory for this purpose because it is not crucially important that every packet arrives. Missing data packets, however, should not normally happen on dedicated network link and therefore this event may be used as an

additional test of the network link. That is the amount of missing data packets may be used as a parameter to indicate to the users the fidelity of the link. Such fidelity may be communicated through a pop-up menu or box on one or more of the users screens. This box may indicate that the network transmissions are not complete and that data is missing. Courses of action may thereafter be recommend, including restarting the system, or reissuing the command . It must be understood, however, that other protocols for data transfer may also be used, other than only UDP.

Page 12, para 3 (once amended) FIG. 2A illustrates further details of the possible system embodiment. The server 200 is installed in the remote clinic operated by the technician 201. In this embodiment, programmer 203 having an ECG interface is a separate device and is connected to server 200. Patient 204 is connected by the ECG cable (not shown) to the interface 203 for the purpose of the ECG recording, while programming wand 205 through an electromagnetic coupling enables, as is well know in the ~~mediela~~ medical device field, the communication with the implanted device (not shown). The server 200 is the most complex component of the system, which provides real-time data about the patient's state, accepts and executes the operator's commands, monitors the system's overall performance and reliability, resolves all dubious situations and acts in emergency situations. The server is designed to take all this responsibility because it is nearest to the patient, and failure of any of the components between it and the patient are least likely. It may be a standard PC computer, but also a "black box" without special screen and command buttons which could confuse the operator 201. A variety of different types of devices may be used

to connect server 200 to the Internet (which usually comprises hubs and routers which are not shown) including modem, ISDN or ATM interface 206. A second device is provided to connect client 208 to the Internet. A modem 207 is illustrated as connecting client 208 to the Internet (of course other devices such as ISDN or ATM interface may also be used.) Advisor 209, being the expert for the particular therapy with the medical device, is the operator of the client computer 208. The client 208 shows to the operator 209 a graphic user interface that visually and functionally mimics the GUI of the implantable device programmer 203. It displays the ECG waveform of the patient, and comprises the controls of the ECG recording and display as well as the implantable device programming commands.

Page 15, para 1 (once amended) FIG. 3B is a schematic block diagram of the steps undertaken for the communication with a medical device using the system of the present invention disclosed in FIG. 2B. It is assumed for this illustration that the programmer and the client are a single hardware device. Of course, this is not per se required and separate and discrete devices may also be used. As seen at 3-1, the server is logged into. Thereafter, the server software application is begun at 3-2, whereby server waits for dial-up network connection call. At any time, at 3-3 the patient activates his device and the client application starts at 3-4. Patient puts the programming wand above the implanted device and client identifies medical device through uplinking in identified step, step 3-5. Patient connects the ECG cable to his body starting to record the ECG waveform at 3-6 supplying the client with the ECG signal at 3-7. At 3-8 client makes a call sending the appropriate request to the server

in order to establish the dial-up network connection whereby starting to send a real-time ECG waveform in UDP packets as well as the patient data. As discussed above, this takes place via the Internet using various communication protocols, including TCP/IP. The server identifies the client at 3-9 and the real-time ECG waveform is continuously displayed at 3-10 within the server GUI together with the all of the patient data. Client sends the device identification at 3-11 and server starts the software application for the specific device at 3-12. This causes the change of the GUI at 3-13 bringing display of the additional menus and buttons for interrogation and programming of the specific device. After unplink, device has automatically completed the telemetry measurements at 3-17. Operator of the server points to the appropriate button at 3-14 putting an interrogation and telemetry request at 3-15 to the client through the network which receives and interprets this command at 3-16. As seen, diagnostic memory content and telemetry results are prepared at 3-18 for the processing in order to make a Java applet at 3-19 and to send it via network. The server receives and interprets the applet at 3-20 and displays the telemetry and diagnostics screen at 3-21. This may be the screen such as the QuickLook™ feature of the Vision™ software, the product of the Medtronic, Inc.

Page 16, para 3 (once amended). FIG. 6 depicts the various types of information transferred between client, server and device as well as the protocol used for the transmission. As discussed above, the system preferably uses at least two communication channels, the first channel requiring a receipt returned. The second data channel, in contrast, does not provide a receipt that the information was properly received.

As seen, the system preferably uses a non-receipt information protocol for information such as the QRS signals (ventricular depolarization) of a pacemaker. Such information is ongoing display information in which the absence of data may be readily ascertained as well as not immediately crucial to device operation. Other information, such as commands, are transmitted using a protocol in which a receipt of acceptance is provided.

Page 18, para 2 (once amended). FIG. 9 depicts an additional system to the present system. The present system permits communication to be made over dispersed mediums such as an internet. As such it permits ready access by a multiple number of clients to a single server. Thus, as seen, the system could permit, in addition to client A, depicted here as 4 (and which is communicated with and to in the same manner as that discussed with regards to FIG. 1), the additional provision of client B 9-2 and client C 9-3. These additional clients may have varying means of access to the server and, thus, to the programmability of the device. For example, client B may have access to be only an observer while client C may be provided to be an observer/client with the additional ability to interrogate the device as well as do memory and telemetry read out. In this environment, moreover, server 3 plays a more active role. For example, as discussed above each client may have various level of access. To permit this, server 3 provides differing GUI applets to the differing authorized clients. For example, only one authorized client would have the possibility to control the programming session i.e. program the therapy device and to see the private patient data. Other clients would only have the possibility to observe what is the authorized

client doing. They could also save the interrogated program and telemetry data as well as the ECG, IEGM (Intracardiac ElectroGraM) and marker channel waveforms in their computers for the later recall for the education purpose.

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Page 21, para 1 (once amended). ATM brings completely new possibilities for telemedicine and particularly for the implantable devices follow-up. IP over ATM will be the most important variant of the infrastructure utilized for the public network. ATM is a connection-oriented technology utilizing the Layer 2 cell switching of the Open Systems Interconnection protocol that is the hardware based. In contrary to that, IP is a connectionless protocol whereby IP networks use software-based Layer 3 packet routing. From the practical point of view, the most convenient for teleprogramming would be the ATM connection between the client and the server, despite of the fact which one of the two comprises the programmer. It may happen that commercial interest will rise among the medical institutions and small physicians offices in such a manner that they will have multiple tasks and therefore cheap ATM connection for teleradiology, telepathology, teleconference, telesurgery and other various telemedicine applications. Nevertheless, several IP over ATM protocols are in development. Particularly the Internet Engineering Task Force (IETF) has been active developing the RFC 1577 being the first true IP over ATM technology called Classical IP (CLIP) and emulating the IP subnetwork in an ATM infrastructure. One or more logical internetworking subnetworks are connected to a backbone subnetwork comprising routers attached to an ATM node. ATM Forum has developed LAN emulation (LANE) providing the protocols used by the clients to dynamically setup

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and tear-down ATM data carrying connections over the backbone network. It has a lack of security standards for the public networks. Ipsilon Networks developed the IP switching being actually a combination of intelligent IP routing with high-speed ATM switching, having major lack of scalability. ATM Forum developed a novel approach to the overlay combining the LANE dynamic setup process with the another routing protocol called Next Hop Resolution Protocol (NHRP). Finally, Multiprotocol Label Switching (MPLS) is the emerging technology of the IETF utilizing the concepts of the IBM's label switching in ARIS <u>(Academic Research Information System)</u> protocol and of the ~~TAG~~ <u>Tag</u> switching of Cisco.

Serial No. 09/348,506 Art Unit 2152 Docket No. P-8027.00

Amended Claims Version With Markings To Show Changes Made

1. (cancel) ~~A system for remote communication with a medical device comprising~~
~~a medical device, the medical device adapted to be implanted into a patient;~~
~~a server PC communicating with the medical device, the SPC having means for transmitting data across a dispersed data communication pathway (Internet); and~~
~~a client PC having means for receiving data transmitted across a dispersed communication pathway from the SPC.~~

2. (cancel) ~~The system according to claim 1 wherein the SPC having means for transmitting data across a dispersed data communication pathway (Internet) along a first channel and a second channel; and~~
~~the client PC having means for receiving data transmitted across a dispersed communication pathway from the SPC along a first channel and a second channel.~~

3. (cancel) ~~The system according to claim 1 further comprising a programmer, the programmer coupled to the SPC and providing a means for interacting with an medical device.~~

4. (cancel) ~~The system according to claim 3 wherein the means for interacting with an medical device comprise a means for testing the medical device.~~

5. (cancel) ~~The system according to claim 4 wherein the programmer has means for sensing a connection interruption between the client and server or the server and programmer.~~

6. (cancel) ~~The system according to claim 5 wherein the programmer has means for terminating any testing being performed by the medical device should the means for sensing the connection interruption sense a connection interruption.~~

7. (cancel) ~~The system according to claim 3 wherein the means for interacting with an medical device comprise means for interrogating the medical device~~

8. (cancel) ~~The system according to claim 3 wherein the means for interacting with an medical device comprise means for downloading data from the medical device~~

9. (cancel) ~~The system according to claim 3 wherein the means for interacting with an medical device comprise means for uploading data to the medical device~~

10. (cancel) ~~The system according to claim 1 wherein the client PC has means for communicating across a dispersed data communication pathway (Internet) to the SPC.~~

11. (cancel) ~~The system according to claim 1 wherein the client PC has means for classifying client users as either a first client user or a second client user.~~

12. (cancel) ~~The system according to claim 1 wherein the client PC has means for classifying client users as either a first client user or a second client user or a third client user or a fourth client user.~~

13. (cancel) ~~The system according to claim 11 further comprising mean for providing a first user interface to the first client user upon the classification of the client user as a first client user.~~

14. (cancel) ~~The system according to claim 13 further comprising mean for providing a second user interface to the client user upon the classification of the client user as a second client user.~~

15. (cancel) ~~The system according to claim 11 further comprising mean for limiting access to the medical device upon the classification of the client user as a first client user.~~

16. (cancel) ~~The system according to claim 15 wherein the mean for limiting access to the medical device upon the classification of the client user as a first client user comprises mean for permitting the first client user to only observe medical device operation.~~

17. (cancel) ~~The system according to claim 12 further comprising the medical device has means for storing information, and wherein the mean for limiting access to the medical device upon the classification of the client user as a first client user comprises mean for permitting the first client userto only retrieve information stored in the medical device.~~

18. (cancel) ~~The system according to claim 12 wherein the means for classifying client users and limiting access to the medical device based on the classification comprises means for classifying and client users and limiting access to the medical device to only~~

19. (cancel) ~~The system according to claim 1 wherein the means for transmitting data across a dispersed data communication pathway (Internet) comprises means for transmitting data in one or more data packets.~~

20. (cancel) ~~The system according to claim 19 wherein the one or more data packets each have a confirmation receipt whereby the client, upon receipt of each of the one or more data packets, transmits back to the SPG that the one or more data packets was received.~~

21. (cancel) ~~The system according to claim 19 wherein the one or more data packets do not have a confirmation receipt.~~

22. (cancel) ~~The system according to claim 1 wherein the means for transmitting data across a dispersed data communication pathway (Internet) comprises means for transmitting data in one or more data packets using a first data protocol and a second data protocol.~~

23. (cancel) ~~The system according to claim 22 wherein second data protocol includes data packet receipt information.~~

24. (cancel) ~~The system according to claim 1 wherein the server has means for accepting a first handshake data packet from the client.~~

25. (cancel) ~~The system according to claim 1 wherein the first handshake data packet from the client instructs the server to only accept data from the IP address of the client.~~

26. (cancel) ~~The system according to claim 1 wherein the server has means for limiting the acceptance of instructions to the server by the client at the first IP address.~~

27. (cancel) ~~The system according to claim 1 wherein the SPC has means for communicating to the medical device through an electromagnetic coupling~~

28. (cancel) ~~The system according to claim 27 wherein the electromagnetic coupling comprises a head transmitting and receiving electromagnetic signals to the medical device~~

29. (cancel) ~~The system according to claim 1 wherein the SPC has means for transmitting an applet to the client.~~

30. (cancel) ~~The system according to claim 29 wherein the applet comprises an executable program which performs tasks on the client without having to send a request back to the server.~~

31. (cancel) ~~The system according to claim 1 wherein the medical device has means for generating Java applets.~~

32. (cancel) ~~The system according to claim 1 wherein the server has means for determining the delay between data sent from the server to its receipt by the client, the client having means for displaying to a user the determined delay at pre selected times.~~

33 (cancel) ~~A system for communicating with an medical device comprising:~~

~~a programmer, the programmer receiving data from an implanted device;~~

~~a means for dis-assembling the received data into formatted packets of data for transmission through a dispersed communication pathway (Internet);~~

~~means for transmitting the formatted through a dispersed communication pathway (Internet).~~

34. (cancel) ~~The system according to claim 33 further comprising a means for re-assembling formatted packets of data into re-produced data, the re-produced data corresponding to the received data.~~

35. (cancel) ~~The system according to claim 34 further comprising a PC to display the re-produced datawherein the PC has inputs to input commands to the implanted device.~~

36. (added) A method for remote communication over a network between a programmer in telemetry communication with an implantable medical device and client computer, comprising:

transmitting and receiving data between a programmer and an implantable medical device;

transmitting and receiving data between the programmer and a server;

transmitting and receiving a first data stream between the server and a client computer over a network wherein the client computer sends a receipt upon receiving the first data stream from the server and the server sends the receipt upon receiving the first data stream from the client computer; and,

transmitting a second data stream between the server and the client computer over a network wherein the server sends the second data stream to the client computer and the client computer sends the second data stream to the server and transmitting the second data stream occurs free from sending receipts.

37. (added) The method as in claim 36 wherein the first data stream uses a Transmission Control Protocol / Internet Protocol (TCP/IP) containing both a sender's Internet address and a receiver's Internet address.

38. (added) The method as in claim 36 wherein the second data stream transmits data using User Datagram Protocol / Internet Protocol (UDP/IP) containing a receiver's Internet address.

39. (added) The method as in claim 36 wherein the second data stream is a real-time ECG waveform from the implantable medical device.

40. (added) The method as in claim 39 wherein the real-time ECG waveform is composed of QRS signals.

41. (added) The method as in claim 39 wherein the real-time ECG waveform is an ongoing display where absence of data is readily ascertainable and not crucial to implantable medical device operation.